

**REMARKS**

The Office Action dated September 2, 2003 has been carefully considered. While it is believed that many of the claims would have been patentable over the newly cited prior art, in an effort to advance prosecution, Applicant has amended claims 39, 60, 80 and 82 in a manner which is believed to eliminate any doubt about the patentability of these claims. Turning now to the rejections, Claims 39, 40, 53-55, 60-62, 67 and 68 were rejected under 35 U.S.C. 102 (e) as anticipated by Nelson Patent No. 6,447,539. In particular, the Examiner relied upon Fig. 16 of Nelson and characterized No. 154 of Nelson as "a plug member." However, element 154 of Nelson is characterized by Nelson himself as a "tubular member," *e.g.*, at Col. 17, lines 32, 38 and 46. In fact, element 154 is simply a portion of the length of conduit 140 and, as shown in Fig. 16, conduit 140 has two open ends with a valve 144 located about half way between the open ends. Thus, device 140 of Fig. 16 of Nelson is not an apparatus for sealing a passage through tissue, but rather a conduit which provides a path through tissue, *i.e.*, just the opposite of the claimed subject matter.

In addition, the rejected claims have now been amended to recite that the claimed subject matter is an improvement in an apparatus for sealing a passage through tissue which communicates with a body lumen. The Examiner had previously taken the position that the preamble of the claims was simply a statement of use. However, particularly in light of the amendments to the preamble, it is respectfully submitted that the preamble of the claims at issue

does constitute a limitation in the claims and is not a mere statement of use. The claims as presently drafted are similar to those involved in *Rowe vs. Dror*, 112 F.3rd 473, 479, 42 U.S.P.Q. 2nd 1550 (Fed. Cir. 1997) where the preamble of the claim recited “In a balloon angioplasty catheter ... the improvement comprising: ...” The court first noted at 112 F.3rd 478:

“This appeal depends on whether the claimed phrase ‘balloon *angioplasty* catheter’, which appears only in the claim preamble, is or is not an affirmative limitation of the claims.”

At page 479, the Court first took note of the fact that the claims were drawn in the “Jepson” form which itself suggests the structural importance of the recitation found in the preamble. The Court then held:

“When this form is employed, the claimed preamble defines not only the context of the claimed invention, but also its scope.”

The Court also made reference to § 608.01(m) of the Manual of Patent Examining Procedure and quoted that portion of the MPEP as follows:

“The preamble of this form of claims is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination.”

Thus, the adoption of the Jepson form of claim is itself sufficient to make it clear that the preamble is a part of the claim and that a determination of patentability over the prior art must include the preamble as part of what is claimed. In addition, the rejected claims have been amended to recite that the lumen which extends from the distal region to the proximal region of the recited apparatus is a “position indicating lumen.” Support for this limitation may be found,

*e.g.*, at page 14, lines 10-15. Plainly, the lumens in the conduits of Nelson are not position indicating lumens. The position indicating function of the lumen of the present invention arises by reason of blood flow occurring when the opening in the distal region of the plug reaches the interior of the blood vessel or other body lumen such that blood flows into the distal opening, through the lumen and out of the proximal opening thereby providing a visual indication of the position of the device when the blood flows out of the opening in the proximal region.

Claims 39, 40, 53, 54, 60-62 and 67 have been rejected under 35 U.S.C. 102(e) as being anticipated by Freeman Patent No. 6,306,114. It is respectfully submitted that the preamble of the rejected claims must be included as a limitation in the claims for the reasons stated above and that the claims plainly patentably distinguish from the plug for lacrimal duct occlusion disclosed by Freeman. As disclosed in the Freeman patent, the purpose of Freeman's plug is to occlude the flow of tears through the lacrimal duct. This is the antithesis of Applicant's device which is designed to seal a passage through tissue which communicates with a body lumen (such as the lacrimal duct) without blocking or occluding flow through the body lumen. Furthermore, the lumen in the plug of Freeman is not a position indicating lumen as recited in the claims of the present application. Thus, it is believed that the rejected claims, as amended, are not anticipated by Freeman.

Claim 82 has been rejected as anticipated by Frassica Patent No. 5,989,230. The Examiner correctly observes that Claim 82 did not recite the lumen connecting the distal opening

with the proximal opening as recited in the remaining claims. This was an oversight on Applicant's part for which Applicant apologizes. It was intended to include this recitation in the Amendment filed July 21, 2003. Thus, Applicant is grateful that the Examiner has noted this oversight and has added this recitation to the claim.

It is believed that Claim 82, as amended, is patentable over Frassica both for the reasons set forth with regard to the remaining claims in the Amendment filed July 21, 2003, which are incorporated herein by reference, and by reason of the additional amendments made in the present response.

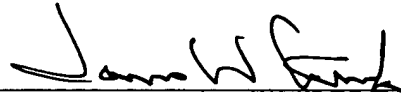
Claims 44 and 65 have been rejected as obvious over Nelson in view of Barry Patent No. 5,492,763. It is respectfully submitted that, given the deficiencies of Nelson explained above, the disclosure by Barry of the use of infection resistant materials in medical devices does not remedy any of the deficiencies of Nelson. Thus, it is believed that Claims 44 and 65 are patentable over the combination of Nelson and Barry.

It is believed that all of the claims pending in this application are patentable and a favorable action is respectfully solicited.

Respectfully submitted,

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Dated: December 2, 2003

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